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10/575,333

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Nicolas Bihoreau

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EXAMINER

WEHBE, ANNE MARIE SABRINA

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,333	<b>Applicant(s)</b> BIHOREAU ET AL.	
	<b>Examiner</b> Anne Marie S. Wehbe	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to methods for preparing a humanized or human chimeric monoclonal antibody with high effector activity comprising producing monoclonal antibodies from different sources, measuring the fucose and galactose content in the Fc region and selecting antibodies with a fucose/galactose content ration is less than or equal to 0.6.

Group II, claim(s) 16-20, and 57, drawn to methods for increasing the effector activity of immunologically functional molecules comprising increasing the galactose content and/or reducing the fucose content of the molecules.

Group III, claim(s) 21-26, drawn to cell derived from the YB2/0 cell line comprising a vector encoding an antibody with a fucose/galactose content ratio of less than or equal to 0.6.

Group IV, claim(s) 27, drawn to a method for preparing antibodies with a fucose/galactose content ratio of less than or equal to 0.6 comprising culturing a cell derived from the YB2/0 cell line comprising a vector encoding an antibody with a fucose/galactose content ratio of less than or equal to 0.6.

Group V, claim(s) 28-32, drawn to therapeutic antibodies having high effector activity with a fucose/galactose content ratio of less than or equal to 0.6.

Group VI, claim(s) 33-38, drawn to methods of administering an antibody having high effector activity with a fucose/galactose content ratio of less than or equal to 0.6 to a subject in need thereof.

Group VII, claim(s) 39-50, drawn to methods for preparing a humanized or human chimeric monoclonal antibody with low effector activity comprising producing monoclonal antibodies from different sources, measuring the fucose and galactose content in the Fc region and selecting antibodies with a fucose/galactose content ration is larger than 0.6.

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Group VIII, claim(s) 51-54, and 57, drawn to methods for reducing the effector activity of immunologically functional molecules comprising reducing the galactose content and/or increasing the fucose content of the molecules.

Group IX, claim(s) 55, drawn to an antibody having low effector activity with a fucose/galactose content ratio is larger than 0.6.

Group X, claim(s) 56, drawn to a method of administering an antibody having low effector activity with a fucose/galactose content ratio is larger than 0.6. to a patient in need thereof.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: there is no common feature among all of groups I-X, particularly as groups I-VI involve antibodies having high effector function and groups VII-X involve antibodies having low effector function. Further, the prior art teaches antibodies with high and low effector function which inherently comprise fucose/galactose content ratios of less or more than 0.6 respectively, see WO 01/77181 A (Glacet et al.) 18 October 2001, cited in the International Search Report and IPER for PCT/FR2004/002686 for which this application is the national stage application (a copy is Glacet et al. attached to this action as no IDS or prior art have been made of record in this application).

It is also noted that 37 CFR 1.475 states that an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

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(4) A process and an apparatus or means specifically designed for carrying out the said process;

or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

From the above, it is clear that multiple combinations are not allowed. Further, the allowed combinations do not include multiple products, multiple methods of using said product, and methods of making multiple products as claimed in the instant application, see MPEP § 1850 and 37 CFR 1.475.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1) for Groups I and VII, species of “sources” for the monoclonal antibodies

a) non-human animal

b) plant

c) mammalian cells

d) insect cells

e) plant cells

f) bacterial cells

g) yeast cells

2) for Group VI, species of conditions to be treated

h) allo-immunization

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i) autoimmune disease

j) cancer

k) virus

l) bacteria

m) polymorphisms of CD16

3) for Group X, species of conditions to be treated

n) autoimmune disease

o) allo-immunization

p) PTI

q) graft rejection

r) allergy

s) asthma

t) dermatitis

u) urticarias

v) erythemas

w) inflammatory diseases.

If applicant elects groups I, VI, VII or X, applicant is required, in reply to this action, to elect a single species from the appropriate listing above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the “sources” represents an organism or cell with materially different physical, chemical, and structural properties; each of the diseases/conditions to be treated represent conditions with materially different etiologies and symptoms.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Any inquiry concerning



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this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

*/Anne Marie S. Wehbé/*

Primary Examiner, A.U. 1633